

Notice of Allowability

Application No.

10/511,758

Applicant(s)

BERGMANN ET AL.

Examiner

Christina Borgeest

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Response to Non-final Office action filed 20 September 2007.
2. ☒ The allowed claim(s) is/are 19-27, renumbered as 1-9, respectively.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: Applicants' amendment has overcome rejections made under 35 U.S.C. 112, 2nd paragraph at pages 3-6 of the previous Office action mailed 21 March 2001. Furthermore, the amendment overcomes the rejection under 35 U.S.C. 102 because the prior art does not teach a link between diagnosis of sepsis and LASP-1, but rather, taught a link between LASP-1 and prognosis of breast cancer. The rejections under 35 U.S.C. 101 and 112, first paragraph no longer apply to the amended claims, which no longer encompass measuring LASP-1 for the purpose of "medical diagnosis" of any condition. Applicants have amended the claims to specifically focus on diagnosis of sepsis and the claims also recite measuring at least one further biomarker for sepsis in a blood or serum sample in a patient suspected of having sepsis, thus Applicants have a specific patient population, and they are not relying only on LASP-1 measurements, but also procalcitonin (see claim 26), which is a useful and well known marker for sepsis (see Dayer et al. Nat Clin Pract Rheumatol. 2007; 3: 512-20). Finally, Figures 3 and 4 show that only 4.4% of non-sepsis patients have a positive result (a small false positive rate indicates screen is specific) and 0% in the negative range (a small false negative rate indicates the screen is very sensitive). Because there is no art linking the diagnosis of sepsis with LASP-1, there is no suggestion of obviousness.

Closest Prior Art

Tang et al. (U.S. Patent No. 6,919,193, issued 19 July 2005, effective filing date, 30 January 2001) teaches at Table 2 the protein having SEQ ID NO: 86 (Accession Number AL365412), which is "similar to LASP-1" (see column, 95, Table 2). In addition, the '193 Patent teaches at column 47, lines 7-35, that "[compositions] of the present invention may also exhibit anti-inflammatory activity...utilized to prevent or treat conditions such as...sepsis...". Nevertheless, since the '193 only teaches a protein having similarity to LASP-1, and has no teaching of diagnosis of sepsis, there is no teaching or suggestion that the measurement of LASP-1 in blood or serum from a patient suspected of having sepsis could be diagnostic therefor. Tang et al. (U.S. Patent No. 6,743,619, issued 1 June 2004, filed 30 January 2001) contains the same disclosure as the '193 patent.

Any comments considered necessary by Applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 7:00am - 1:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest, Ph.D.

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646